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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,651	04/17/2007	Borut Furlan	33578US-PCT	5011
83721	7590	04/28/2010		
Lek (Slovenia) - LUEDEKA, NEELY & GRAHAM, P.C.				
P.O. BOX 1871				
Knoxville, TN 37901				
EXAMINER				
KATAKAM, SUDHAKAR				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
04/28/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,651

Applicant(s)

FURLAN ET AL.

Examiner

SUDHAKAR KATAKAM

Art Unit

1621

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 8 March 2010 is acknowledged.
2. Applicants' arguments for the 103(a) rejection are not found persuasive and therefore, the previous rejection made on 7 Oct 2009 has been maintained.

Response to Arguments

3. Applicant's arguments filed on 8 March 2010 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' argument that **Hoorn et al** fails to teach molar excess of 1-(2-bromoethoxy)-2-ethoxybenzene in the preparation of tamsulosin hydrochloride.

The examiner contends, however, that the concentrations of reactants are optimizable for a given reaction process. Moreover, the purity of the tamsulosin hydrochloride at more than a 99.9% in the process of **Hoorn et al**, which also reads the purity of the claimed process. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed concentration range result in some unexpected property over the prior art. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

The examiner acknowledges applicants argument that their claim requires a measurable amount of the overalkylated compounds in the purification reaction mixture.

The examiner contends, however, that **Hoorn et al** teach 99.9% purity of tamsulosin hydrochloride in their preparation process. Since the prior art teaches same starting materials and end product, the remaining 0.1% consists of overalkylated products. Therefore, it is expected that the purification reaction mixture inherently comprises of similar impurities. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

With regard to newly added claims, **Hoorn et al** teach the purity of the tamsulosin hydrochloride at more than a 99.9% in their process. The claim 15 requires at least 75% tamsulosin HCl and at least some measurable amount of overalkylated products comprising less than 5%. This claimed range still overlaps with the range taught by the **Hoorn et al**. Please note that in the **Hoorn et al** product purity, the overalkylated products inherently present an amount of less than 0.1%.

Applicants show how the cited references differ from the instant invention, but the obviousness test under 35 U.S.C. 103 is whether the invention would have been obvious in view of the prior art taken as a whole. **In re Metcalf et al. 157 U.S.P.Q. 423.**

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made, to use the teachings of the above cited references

and to arrive at instant applicants composition or reaction mixture with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-4 and 15-16 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **Hoorn et al** (US 6,835,853).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

8. No Claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-079. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/

Examiner, Art Unit 1621

/Peter G O'Sullivan/

Primary Examiner, Art Unit 1621